GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2025

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HOUSE BILL DRH40336-MRa-91

Short Title:	Ensure Access to Biomarker Testing.	(Public)
Sponsors:	Representative Wheatley.	
Referred to:		

A BILL TO BE ENTITLED

AN ACT TO ENSURE ACCESS TO AN EARLY AND ACCURATE DIAGNOSIS OF DEMENTIA IN ORDER TO IMPROVE ACCESS TO CARE AND SUPPORT SERVICES FOR, ENHANCE THE QUALITY OF LIFE OF, AND REDUCE THE FINANCIAL IMPACT OF THE CONDITION ON NORTH CAROLINIANS.

The General Assembly of North Carolina enacts:

PART I. HEALTH BENEFIT PLAN COVERAGE OF BIOMARKER TESTING

SECTION 1.1.(a) Article 3 of Chapter 58 of the General Statutes is amended by adding a new section to read:

"**§ 58-3-216. Coverage of biomarker testing.**

(a) The following definitions apply in this section:

(1) Biomarker. – A characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medication being considered for use or already being administered. This term incudes gene mutations, characteristics of genes, and protein expression.

(2) Biomarker testing. – The analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. This term includes single-analyte tests, multi-plex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

(3) Consensus statement. – A statement that is developed by an independent multidisciplinary panel, aimed at specific clinical circumstances, and based upon the best available evidence for the purpose of optimizing the outcomes of clinical care.

(4) FDA. – The United States Food and Drug Administration.

(5) Reserved for future codification purposes.

(6) Independent multidisciplinary panel. – A multidisciplinary panel of experts that utilizes a transparent methodology and reporting structure and that has a conflict of interest policy.

(7) Independent organization or medical professional society. – An organization or medical professional society that utilizes a transparent methodology and reporting structure and that has a conflict of interest policy.

(8) Reserved for future codification purposes.

(9) Nationally recognized clinical practice guidelines. – Evidence-based clinical practice guidelines developed by independent organizations or medical professional societies that establish standards of care that are informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and that include recommendations intended to optimize patient care.

(b) A health benefit plan shall provide coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate care management, or ongoing monitoring of an insured's disease or condition when the testing is supported by medical and scientific evidence. At a minimum, any of the following shall be considered support for biomarker testing:

(1) Label indications for a test that has been FDA-approved or FDA-cleared.

(2) Indicated tests for an FDA-approved drug.

(3) Warnings and precautions on an FDA-approved drug label.

(4) National coverage determinations developed by the Centers for Medicare and Medicaid Services.

(5) Local coverage determinations developed by a Medicare Administrative Contractor.

(6) Nationally recognized clinical practice guidelines and consensus statements.

(c) Coverage required under this section shall be provided in a manner that limits disruption in patient care, including the need for multiple biopsies or biospecimen samples."

SECTION 1.1.(b) G.S. 58-3-215, as amended by subsection (c) of this section, reads as rewritten:

"**§ 58-3-215. Genetic and biomarker information in health insurance.**

(a) Definitions. – ~~As used~~ The following definitions apply in this section:

(1) Biomarker. – A characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medication being considered for use or already being administered. This term incudes gene mutations, characteristics of genes, and protein expression.

(1a) ~~"Genetic information" means information~~ Genetic information. – Information about genes, gene products, or inherited characteristics that may derive from an individual or a family member. "Genetic information" does not include the results of routine physical measurements, blood chemistries, blood counts, urine analyses, tests for abuse of drugs, and tests for the presence of human immunodeficiency virus.

…

(c) No insurer ~~shall:~~shall do any of the following:

(1) Raise the premium or contribution rates paid by a group for a group health benefit plan on the basis of genetic or biomarker information obtained about an individual member of the group.

(2) Refuse to issue or deliver a health benefit plan because of genetic or biomarker information obtained about any person to be insured by the health benefit plan.

(3) Charge a higher premium rate or charge for a health benefit plan because of genetic or biomarker information obtained about any person to be insured by the health benefit plan.

…."

SECTION 1.1.(c) G.S. 58-3-215(a)(2) and G.S. 58-3-215(a)(3) are repealed.

SECTION 1.1.(d) This section is effective October 1, 2025, and applies to insurance contracts issued, renewed, or amended on or after that date.

SECTION 1.2.(a) G.S. 58-50-61 reads as rewritten:

"**§ 58-50-61. Utilization review.**

(a) Definitions. – As used in this section, in G.S. 58-50-62, and in Part 4 of this Article, the term:

…

(16a) Urgent healthcare service. – A healthcare service with respect to which the application of the time periods for making a non-expedited utilization review that, in the opinion of a medical doctor with knowledge of the covered person's medical condition, could either (i) seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function or (ii) subject the covered person to severe pain that cannot be adequately managed without the care or treatment that is the subject of the utilization review. The term urgent healthcare service includes mental and behavioral healthcare services.

…

(f) Time Lines for Prospective and Concurrent ~~Reviews.~~ Utilization Reviews Based Upon Type of Healthcare Service. – As used in this subsection, the term "necessary information" includes the results of any patient examination, clinical evaluation, or second opinion that may be required. ~~Prospective and concurrent determinations shall be communicated to~~ The time line for completion of a prospective or concurrent utilization review is as follows:

(1) Non-urgent healthcare services. – If an insurer requires a utilization review of a healthcare service, then the insurer or its URO shall both render a utilization review determination or noncertification and notify the covered person and the covered person's provider within three business days after the insurer obtains all necessary information ~~about the admission, procedure, or health care service.~~ to make the utilization review determination or noncertification.

(2) Urgent healthcare services. – An insurer or its URO shall both render a utilization review determination or noncertification concerning urgent healthcare services and notify the covered person and the covered person's provider of that utilization review determination or noncertification not later than 24 hours after receiving all necessary information needed to complete the review of the requested healthcare services. If the covered person's provider or the insurer, or the entity conducting the review on behalf of the insurer, do not both have access to the electronic health records of the covered person, then this subdivision shall not apply and the utilization review will be subject to the time line under subdivision (1) of this subsection.

(f1) Utilization Review Determination Notifications. – If an insurer or its URO certifies a ~~health care~~ healthcare service, ~~the insurer shall notify~~ notification shall be sent to the covered person's provider. ~~For~~ If an insurer or its URO issues a noncertification, ~~the insurer shall notify the covered person's provider and send~~ then written or electronic confirmation of the noncertification shall be sent to the covered person's provider and covered ~~person. In~~ person that is in compliance with subsection (h) of this section.

(f2) Concurrent Review Liability. – For concurrent reviews, the insurer shall remain liable for ~~health care~~ healthcare services until the covered person has been notified of the noncertification.

…

(m) Disclosure of Utilization Review Requirements. – Information required to be provided under this section shall be described in detail and in easily understandable language. All of the following apply to an insurer's responsibility to disclose any utilization review procedures:

(1) Coverage and member handbook. – In the certificate of coverage and member handbook provided to covered persons, an insurer shall include a clear and

comprehensive description of its utilization review procedures, including the procedures for appealing noncertifications and a statement of the rights and responsibilities of covered persons, including the voluntary nature of the appeal process, with respect to those procedures. An insurer shall also include in the certificate of coverage and the member handbook information about the availability of assistance from the Department's Health Insurance Smart NC, including the telephone number and address of the ~~Program.~~ program.

(2) Prospective materials. – An insurer shall include a summary of its utilization review procedures in materials intended for prospective covered persons.

(3) Membership cards. – An insurer shall print on its membership cards a toll-free telephone number to call for utilization review purposes.

(4) Website. – An insurer shall make any current utilization review requirements and restrictions readily accessible on its website.

…."

SECTION 1.2.(b) This section becomes effective October 1, 2025, and applies to insurance contracts issued, renewed, or amended on or after that date.

SECTION 1.3.(a) G.S. 135-48.51 reads as rewritten:

"**§ 135-48.51. Coverage and operational mandates related to Chapter 58 of the General Statutes.**

The following provisions of Chapter 58 of the General Statutes apply to the State Health Plan:

(1) G.S. 58-3-191, Managed care reporting and disclosure requirements.

(1a) G.S. 58-3-216, Coverage of biomarker testing.

…."

SECTION 1.3.(b) In accordance with G.S. 135-48.24(b) and G.S. 135-48.30(a)(7) which require the State Treasurer to implement procedures that are substantially similar to the provisions of G.S. 58-50-61 for the North Carolina State Health Plan for Teachers and State Employees (State Health Plan), the State Treasurer and the Executive Administrator of the State Health Plan shall review all practices of the State Health Plan and all contracts with, and practices of, any third party conducting any utilization review on behalf of the State Health Plan to ensure compliance with Section 2 of this act no later than the start of the next plan year.

SECTION 1.3.(c) Effective July 1, 2025, there is appropriated from the General Fund to the Department of State Treasurer the sum of one million dollars ($1,000,000) in recurring funds for each year of the 2025-2027 fiscal biennium to be used to implement the coverage required by this section for the State Health Plan.

SECTION 1.3.(d) Except as otherwise provided, this section becomes effective October 1, 2025, and subsection (a) of this section applies as of the start of the next plan year following the effective date.

PART II. MEDICAID COVERAGE OF BIOMARKER TESTING

SECTION 2.1. The Department of Health and Human Services, Division of Health Benefits (DHB), shall ensure coverage for biomarker testing under the laboratory services clinical coverage policies 1S-1 through 1S-13 to the same extent those services are required to be covered by a health benefit plan under G.S. 58-3-216. DHB shall ensure its policies and procedures for the prior authorization of any service covered under this section are in compliance with Section 2.2 of this act.

SECTION 2.2.(a) For purposes of this section, the term "urgent prior authorization request" is defined as a request for which a time line for decision longer than 72 hours could seriously jeopardize the beneficiary's life, health, or ability to attain, maintain, or regain maximum function, in the opinion of the beneficiary's healthcare provider.

SECTION 2.2.(b) If prior authorization is required for any service covered under Section 2.1 of this act, the time line for completion of a review of that prior authorization request shall be as follows:

(1) For urgent prior authorization requests, DHB shall ensure that the prior authorization request is either approved or denied and notice is given to the beneficiary and beneficiary's healthcare provider within 24 hours after DHB receives all information needed to complete a review of the request for prior authorization.

(2) For non-urgent prior authorization requests, DHB shall ensure that the prior authorization request is either approved or denied and notice is given to the beneficiary and beneficiary's healthcare provider within 72 hours after DHB receives all information needed to complete a review of the request for prior authorization.

PART III. EFFECTIVE DATE

SECTION 3.1. Except as otherwise provided, this act is effective when it becomes law.